UNITED STATES PATENT APPLICATION

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FOR: CLOSURE

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a closure assembly for a thermoplastic tube, and particularly for a blood collection tube.

2. Description of the Prior Art

Evacuated and sealed thermoplastic tubes are used for collecting, storing and transporting specimens of blood. The prior art evacuated blood collection tube is used with double ended needle cannula and a tube holder. One end of the needle cannula projects distally from the tube holder, and the opposed end of the needle cannula projects proximally within the tube holder. This prior art assembly is employed by placing the distal end of the needle cannula into communication with a blood vessel of a patient. The prior art evacuated tube then is urged into the tube holder such that the proximal end of the needle cannula pierces the closure of the blood

collection tube. Low pressure in the evacuated tube facilitates a flow of blood. After a sufficient volume of blood has been collected, the tube is separated from the holder and shipped to a laboratory for analysis.

Closures of prior art blood collection tubes have taken many forms. All such closures must seal the tube sufficiently for maintaining a vacuum prior to use and for retaining the sample of blood prior to analysis. Prior art closures for blood collection tubes also must be pierceable by a needle cannula, and must be removable or openable to permit access by a probe that extracts blood for analysis.

Some prior art blood collection tubes do not adequately protect health care workers from contact with blood. For example, forces exerted by flowing blood can push the prior art blood collection tube axially out of engagement with the needle cannula. Blood then may flow freely from the needle cannula. In other instances, small droplets of blood may be deposited on an accessible outer surface of the closure as the prior art blood collection tube is separated from the needle cannula. Additionally, some prior art closures are removable from the blood collection tube to enable access by a laboratory probe. The removal of a closure from a tube can create a pressure differential that aspirates or sprays droplets of blood from the tube. The sprayed blood can contact a laboratory technician. Still further, the inner surface of the prior art closure is likely to have direct contact with the blood. Some prior art closures are configured to permit contact with this inner surface after the closure is separated from the tube. Any such contact with a blood sample creates the potential for disease transmission.

Blood samples often are subjected to more than one test. For these situations, it is desirable to reseal the blood collection tube between successive tests. Many prior art closures are not configured for resealing after their initial opening or separation at a laboratory.

SUMMARY OF THE INVENTION

The present invention is directed to a closure assembly for a thermoplastic tube, such as an evacuated blood collection tube. The tube includes a closed bottom, a cylindrical side wall and an open top defining an annular top edge.

The closure includes an outer cap that may be formed from a hard plastic such as, polypropylene, polyethylene or polystyrene. The outer cap may be of generally stepped tubular configuration, and may include opposed top and bottom ends. Portions of the outer cap adjacent the bottom end define a mounting skirt. The skirt is dimensioned to telescope over portions of the side wall of the tube adjacent the open top of the tube.

The outer cap of the closure further includes an annular shoulder extending radially inwardly from portions of the skirt remote from the bottom end of the outer cap. The radial dimension of the shoulder exceeds the thickness of the tube. Thus, bottom surface of the annular shoulder lies in juxtaposition to the annular top edge of the tube when the skirt of the outer cap is telescoped over the open top of the tube. The annular shoulder includes an aperture having a diameter that is significantly greater than the cross-sectional dimensions of a needle cannula to be used with the tube. However the aperture in the annular shoulder is significantly smaller than a typical human finger.

The outer cap further includes a safety collar that projects upwardly from radially inner portions of the annular shoulder to the top end of the outer cap. The safety collar defines an inside diameter substantially equal to the inside diameter of the aperture through the annular shoulder. Thus, the safety collar enables a needle cannula to be passed axially therethrough for accessing the tube, while simultaneously preventing inadvertent digital contact with portions of the closure assembly below the annular shoulder of the outer cap.

The closure assembly further includes a laminated seal secured to the bottom face of the annular shoulder and extending continuously across the aperture of the annular shoulder. The laminated seal includes opposed top and bottom faces. The top face of the laminated seal is fused or bonded to the bottom face of the annular shoulder, while the bottom face of the laminated seal is fused or bonded to the annular top edge of the tube. Preferably, bonding forces between the laminated seal and the annular shoulder of the outer cap is significantly greater than bonding forces between the laminated seal and the tube. Thus, the laminated seal will remain attached to the outer cap as the outer cap is pulled upwardly for opening the tube.

The laminated seal preferably comprises a foil layer, such as an aluminum foil. The foil is substantially impermeably to gases, and hence is effective for retaining a vacuum and sterility in the tube prior to use. However, the aluminum foil is easily penetrable by a needle cannula for delivering a sample of blood to the tube. The laminated seal includes layers of a material on either side of the foil for achieving secure bonding of the laminated foil to both the annular shoulder of the outer cap and to the annular top edge of the tube. For example, the bottom surface of the laminated seal may comprise a layer of polyethylene terephthalate (PET) laminated to one surface of the foil. The PET layer is readily bondable to the PET tube. The top surface of

the laminated seal may comprise a thermoplastic layer that is compatible with the material from which the outer cap is formed.

The closure assembly further includes a stopper secured to the bottom surface of the laminated seal. The stopper may be made of a thermoplastic elastomer or a thermoset material and is dimensioned for sealing engagement within the open top of the tube. The stopper provides a liquid seal between the inside diameter of the open end of the tube, thereby allowing the closure to be removed and reused a number of times after blood is drawn into the tube. The stopper preferably has an axial dimension that is sufficient to hold the needle during venipuncture and for preventing the tube from being pushed off the needle in response to forces exerted by the blood flowing into the tube. The thermoplastic elastomer or thermoset material of the stopper also is effective for resealing the needle puncture site through the closure to prevent leakage of blood or other fluid through the stopper.

The closure assembly of the subject invention may be used substantially in a conventional manner, by urging a pointed needle cannula through the safety collar of the outer cap and through the laminated seal and stopper. The vacuum within the tube enables a sample of blood to be collected. The tube then is separated from the needle cannula, and the puncture site that had been created by the needle cannula is self-sealed by the stopper. Thus, an effective liquid seal is provided. Contact with the top surface of the laminated seal is substantially prevented by the safety collar of the outer cap. Thus, direct contact with any blood droplets that may exist on the top surface of the laminated seal is substantially prevented.

The tube with the sample of blood therein may be transported to a laboratory for analysis. A sample in the tube may be accessed by pulling the outer cap of the closure assembly upwardly

relative to the tube. As noted above, the bonding forces between the laminated seal and the outer cap are significantly greater than the bonding forces between the laminated seal and the tube. As a result, the entire closure assembly can be removed from the tube for accessing the sample of blood or other liquid in the tube. Pressure differentials created by removal of the stopper from the tube can cause aspiration of blood. However, any minor spray of blood droplets caused by removal of the stopper will be channeled back toward the tube by the skirt of the outer cap and portions of the laminated seal between the skirt and the stopper. Additionally, the skirt of the outer cap substantially prevents contact with any blood that may be on the bottom surface of the stopper.

A portion of the sample of blood in the tube may be removed for analysis. Remaining portions of the blood or other liquid in the tube may be resealed by merely urging the closure assembly back onto the open top of the tube. The tube may be reopened and resealed repeatedly in accordance with testing demands of the laboratory.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded longitudinal cross-sectional view of a closure assembly of the subject invention and a tube for use with the closure assembly.

FIG. 2 is a longitudinal cross-sectional view of the closure assembly secured to the tube.

FIG. 3 is a cross-sectional view of the laminated seal of the closure assembly.

FIG. 4 is a cross-sectional view similar to FIG. 2, but showing the closure assembly separated from the tube for providing laboratory access to the contents of the tube.

FIG. 5 is a side elevational view of a subassembly consisting of the laminated seal and stopper.

FIG. 6 is a schematic illustration of an apparatus and process for molding the stoppers to a laminated sheet.

FIG. 7 is a schematic view of a punch apparatus for cutting the laminated sheet and stoppers into the subassembly of FIG. 5.

FIG. 8 is a cross-sectional view similar to FIG. 2, but showing an alternate embodiment.

DETAILED DESCRIPTION

As shown in FIGS. 1 and 2, closure assembly **10** is employed with a blood collection tube **12.** Tube **12** includes a closed bottom **14**, an open top **16** and a cylindrical side wall **18** extending therebetween. Side wall **18** defines an inside diameter "a", an outside diameter "b" and a wall thickness "t" as shown in FIG. 1.

Closure assembly **10** includes an outer cap **20**, a laminated seal **22** and a stopper **24**. Outer cap **20** is unitarily molded from a hard plastic material, such as polypropylene, polyethylene or polystyrene. Outer cap **20** is of a stepped tubular configuration, and includes an open bottom end **26** and an open top end **28**. A substantially cylindrical skirt **30** extends upwardly from open

bottom end **26** and toward top end **28**. Skirt **30** defines an inside diameter "c" which is slightly greater than outside diameter "b" of tube **12**.

Outer cap **20** further includes an annular shoulder **32** extending substantially radially inwardly from the end of skirt **30** remote from bottom end **26** of outer cap **20**. Annular shoulder **32** includes a bottom surface **34** which faces bottom end **26** of outer cap **20** and which is aligned substantially orthogonal to skirt **30**. Bottom surface **34** of annular shoulder **32** defines a radial dimension which is equal to or greater than thickness "t" of side wall **18** of tube **12**. Thus, bottom surface **34** of shoulder **32** can be disposed in juxtaposed relationship to top end **16** of tube **12** when skirt **30** is telescoped over top portions of side wall **18** of tube **12**. Shoulder **32** includes a central aperture **36** defining a diameter "d" which is substantially greater than the diameter of the needle cannula **40** that will be used with tube **12** and closure **20** as illustrated schematically in FIG. 2. However, diameter "d" of aperture **36** in shoulder **32** is sufficiently small to prevent direct digital contact with laminated seal **22**, as explained further below.

Outer cap **20** further includes a generally cylindrical safety collar **42** which extends from radially inner portions of shoulder **32** to top end **28** of outer cap **20**. Safety collar **42** further prevents direct digital contact with laminated seal **22** without impeding passage of needle cannula **40** through closure assembly **10**.

Laminated seal **22** of closure assembly **10** is a thin planar disk having a diameter equal to or slightly less than inside diameter "c" defined by skirt **30** of outer cap **20**. Laminated seal **20** includes a top face **44** and an opposed bottom face **46**. An aluminum foil substrate **48** is defined between the opposed faces of laminated seal **22**, as illustrated in FIG. 3. Top face **44** of laminated seal **22** is defined by a thermoplastic layer **50** laminated to aluminum foil **48**. The

particular thermoplastic that forms layer **50** is selected to be compatible with the thermoplastic material of outer cap **20**. Thus, as explained further herein, outer circumferential region of top surface **44** of laminated seal **22** can be bonded to bottom surface **34** of annular shoulder **32** of outer cap **20**.

Bottom surface **46** of laminated seal **22** is defined by a layer **52** of polyethylene terephthalate (PET). Thus, outer circumferential regions of bottom surface **46** of laminated seal **22** can be bonded to top end **16** of tube **12**.

Stopper **24** is unitarily molded from a thermoplastic elastomer or thermoset material, and effectively defines a short cylindrical plug with a length "e" and an outer diameter "f" approximately equal to or slightly greater than inside diameter "a" of tube **12**. Bottom portions of stopper **24** can be chamfered to facilitate initial insertion of stopper **24** into open top end **16** of tube **12**.

A subassembly **54** comprising laminated seal **22** and stopper **24** is shown in FIG. 4 and can be manufactured as shown schematically in FIGS. 5 and 6. As shown in FIG. 5, a laminate **56** with layers as shown in FIG. 3 may be provided in elongate sheet form and may be incrementally advanceable from feed roller **58** to take-up roller **60**. The rollers may be disposed to incrementally advance laminated strip 56 through an injection mold apparatus **62** having a stationary side **64** and a movable cavity side **66**. The mold apparatus **62** may be closed onto and around laminated strip **56**, and the thermoplastic elastomer or thermoset material may be injected into cavities for molding a plurality of short cylindrical stoppers **24** directly onto strip **56**. The strip **56** with stoppers **24** thereon are incrementally moved from mold apparatus **62** and onto take-up reel **60**. As shown in FIG. 6, take-up reel **60** subsequently may be advanced in proximity to a

punch press **68** which is operative to punch circular disks of strip **56** substantially surrounding stopper **24** to form laminated seals **22** as described above.

Subassemblies **54**, as shown in FIG. 4 may subsequently be positioned in outer cap **20** such that top surface **44** of laminated seal **22** is seated against bottom surface **34** of annular shoulder **32**. Tube **12** then may be evacuated and closure **10** may be mounted on tube **12** such that stopper **24** is sealingly urged into tube **12**, and such that outer circumferential regions of bottom surface **46** of laminated seal **20** are positioned on open top **16** of tube **12**. Heat and pressure then may be applied to closure to create a fusion bond of laminated seal **22** to shoulder **32** of outer cap **20** and to create an induction bond of laminated seal **22** to top end **16** of tube **12**. The bond of laminated seal **22** to outer cap **20** is formed to be significantly stronger than the bond between laminated seal **22** and tube **12**. Thus, closure assembly **10** will remain substantially intact when tube **12** is opened as shown in FIG. 7.

Closure assembly **10** and tube **12** may be used as shown schematically in FIG. 2. More particularly, a needle cannula **40** may be directed substantially axially through safety collar **42**, and then may puncture laminated seal **22** and stopper **24**. Vacuum conditions in tube **12** will cause a flow of blood through needle cannula **40** and into tube **12**. Length "e" of stopper **24** is sufficiently long to create frictional forces against needle cannula **40** that exceed forces exerted by blood flowing into tube **12**. As a result, closure assembly **10** and tube **12** will remain on needle cannula **40** until a sufficient volume of blood has been drawn.

Closure assembly **10** and tube **12** may be withdrawn from needle cannula **40** after a sufficient volume of blood has been accumulated in tube **12**. Stopper **24** will reseal itself for shipment of the sample to a laboratory. The separation of needle cannula **40** from closure **10** may

cause droplets of blood to be deposited on portions of laminated seal **22** adjacent the puncture location. However, safety collar **42** will substantially prevent contact with any droplets of blood that may remain on laminated seal **22**.

The blood in tube **12** may be accessed at a laboratory by merely pulling closure assembly **10** away from tube **12** with sufficient force to overcome friction between stopper **24** and tube **12** and to overcome bonding forces between laminated seal **22** and top end **16** of tube **12**. However, these separation forces are less than the bonding forces between the laminated seal **22** and outer cap **20**. As a result, closure assembly **10** will remain substantially intact, as shown in FIG. 7. The closure assembly may be replaced onto tube **12** after a portion of the blood has been removed for analysis for resealing remaining blood in tube **12** until required for subsequent analysis.

An alternate closure assembly **110** is shown in FIG. 8. Closure assembly **110** includes an outer cap **120** and a laminated seal **122** that are substantially identical to the outer cap **20** and laminated seal **22** as shown in FIGS. 1-7. Closure assembly **110** further includes a stopper **124** that is similar to the stopper **24** described and illustrated above. However, stopper **124** may have an axial length "e_1" less than the axial length "e" of stopper **24** described above. Closure assembly **110** may further include a top seal **126** that may be bonded to center portions of laminated seal **122** and that may be disposed within a lower portion of a safety collar **142** on outer cap **120**. This alternate embodiment provides sufficient gripping of the needle cannula for preventing push-off in response to forces exerted by blood flowing into the tube. However, the shorter axial length of stopper **124** reduces forces required for removing closure assembly **110** or resealing closure assembly **110**.